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(54) Rotary catheter for atherectomy system.

(57) An atherectomy system insertable into a human blood vessel over a flexible guidewire for remotely cutting and removing an obstruction therein, having a diametrical stabilized torque transmitting flexible rotary catheter equipped with a rotary coring means at its distal end and a motor connected to its proximal end.

EP 0 680 730 A2

This invention relates to an atherectomy system.

With age a large portion of the population develops arterial obstructions formed by fats, fibrous material and calcified deposits, resulting in a diminished blood circulation. These obstructions can induce blood clots which further diminish or block the blood flow. When this occurs in the coronary arteries serving the heart muscles it is referred to as a heart attack. Presently such obstructions are bypassed with a graft or they are treated by angioplasty using a catheter equipped with a balloon which is inserted, over a flexible guidewire, into the obstruction through the arterial system and then inflated to dilate the obstructions lumen. Problems with this treatment are that it injures the arterial wall and may burst it. In certain cases it is ineffective. It creates a rough lumen. It does not remove the obstructing material out of the vascular system and may even release obstruction material into the vascular system. Thus, angioplasty during a heart attack carries the risk of dislodging particles of the blood clot and allowing it to move down stream creating further, potentially critical damage.

EP-A-358825 discloses an atherectomy system insertable into a human blood vessel for coring and removing an obstruction therein comprising a flexible guidewire insertable into said blood vessel, a flexible rotary catheter having a continuous passage therethrough is rotatably disposed and slidable over said flexible guidewire, said flexible rotary catheter having proximal and distal ends, a rotary coring means for cutting and ingesting obstruction material located at said distal end, a coupling means for rotating said flexible rotary catheter around said flexible guidewire located at said proximal end, means for diametrically stabilizing and means for transmitting torque in the form of closely spaced windings having distal and proximal edges, said windings forming a skeleton of said flexible rotary catheter and inclined plane means to assist in pulling the obstruction material into the catheter.

EP-A-254414 also discloses an atherectomy system with a continuous passage having an auger formed on the distal end of the guidewire to mechanically convey obstruction material into the continuous passage.

An object of the present invention therefore is to provide a flexible torque transmitting rotary catheter for an atherectomy system which can be percutaneously or intra-operatively introduced into the vascular system for cutting and removing an obstruction therein. The flexible rotary catheter is insertable and rotatable over a flexible guidewire and transmits rotation and torque to rotary coring means at its distal end from a motor affixed to its proximal end.

A further object of the present invention is to provide a flexible rotary catheter which will positively remove from the human body the obstruction material, including blood clots if present, while creating a smooth lumen, and minimizing injury to the blood vessels wall.

A further object is to provide a system that can be used during a heart attack to provide immediate relief and a long term correction of the diseased arterial site.

The flexible rotary catheter should lend itself to be producable in diameters down to around 1mm (millimeter) and a length of around a meter to be able to reach and enter small and remote blood vessels. Preferably, the procedure using the atherectomy system would resemble angioplasty so that present skills of the medical staff can be utilized.

The flexible rotary catheter should be simultaneously flexible and capable of transmitting torque so that when it is introduced percutaneously to treat an obstruction in a remote artery, for example a coronary artery, it can assume a tortuous path of the vascular system including some sharp turns found in the coronary vascular system.

The present invention overcomes the problems of the prior art by providing inclined plane means provided by the proximal edges of the closely spaced windings for contacting and assisting the obstruction material in moving proximally in the continuous passage.

These and other objects of the invention will become apparent from the following description of the preferred embodiments by way of example only with reference to the accompanying drawings.

FIGURE 1 is a general view of an atherectomy system being inserted into an obstructed human coronary artery. The atherectomy system is introduced into the vascular system percutaneously at the groin area and is snaked through the arterial system to reach the work site where the obstruction is about to be removed;

FIGURE 2 is a cross sectional view of the proximal and distal ends of the atherectomy system with its distal end inserted into an obstructed coronary artery. The general positioning of the parts corresponds to their position in Figure 1. Due to space limitations on the drawing sheets a segment or segments of the atherectomy system and flexible rotary catheter are omitted and in Figure 2 the mid section of the system is represented by a phantom line;

FIGURE 3 is a sectioned view of a first embodiment of the rotary catheter;

FIGURE 4 is a cross sectional view of the first embodiment as viewed along a line 4-4 marked on Figure 3;

FIGURE 5 is a cross sectional view of the first embodiment as viewed along line 5-5 on Figure 3;

FIGURE 6 is a cross sectional view of a second embodiment of the flexible rotary catheter;

FIGURE 7 is an end view of the second embodiment as viewed along a line 7-7 marked on Figure 6; and

FIGURE 8 is a cross sectional view of the second embodiment as viewed along a line 8-8 marked on Figure 6.

Figure 1 shows a general view of an atherectomy system 10 which is percutaneously introduced into a human femoral artery 11 at the groin area, and its distal end is snaked through the arterial system to reach a work site in a coronary artery 12.

Figure 2 shows an enlarged cross sectional view of a proximal end 13 and of a distal end 14, of the system 10. The distal end is inserted into the diseased coronary artery 12 (as shown in Figure 2 the atherectomy system comprises several elongated parts in a nested relationship, and their ends shall be referred to as "distal" meaning the end which goes into the vessel and "proximal" meaning the other end, thus, "distal direction" or "distally" shall indicate a general direction from the proximal end to the distal end, and "proximal direction" or "proximally" shall refer to an opposite direction. It should also be noted that the same numbers are used to indicate the same items throughout the Figures) containing a blood clot 15' seated on an atherosclerotic obstruction 15. The mid portion of the atherectomy system is represented by a phantom line 16.

The system 10 comprises a flexible guidewire 17 having a section at its distal end shaped as an auger 18. The flexible guidewire is designed to be insertable through the human vascular system.

A flexible rotary catheter 19 has a wall 20 defining a longitudinal channel 21. The catheter 19 is rotatable and slidable over the flexible guidewire 17. A rotary coring means in the form of a tubular blade 22 is located at the distal end of the flexible rotary catheter 19. The tubular blade 22 defines a through hole 23 which forms with the channel 21 a continuous passage for accepting the obstruction material ingested into the through hole (the term rotary coring means as used herein refers to a tubular blade with a smooth or toothed cutting edge, as shown in the drawings accompanying this application or to coring means such as a blade with inwardly bent teeth or to a heated tubular blade, an expandable tubular blade or a radiation emitting blade. Some of these rotary coring means are incorporated into, or are part of, the distal end of the flexible rotary catheter and have no discrete internal wall of their own, in which case the continuous passage consists of the channel 21).

A motor 24 has a hollow tapered shaft 25 which couples it to the proximal end of the flexible rotary catheter through a matching tapered seat 30 for rotating it around the flexible guidewire 17.

A sleeve 26 introduces the flexible rotary catheter into the vascular system and may be extended distally to separate the arterial wall from the rotating catheter and to deliver contrast and/or irrigating fluid to the work site. The sleeve 26 may be formed to a desired shape and serve as a guiding catheter and assist in guiding the system through the vascular system to the work site. A port 27 is provided to accept fluids for delivery through the sleeves distal end and a seal 31 prevents the fluids from escaping out of the proximal end of the sleeve.

A rotary joint 28 has a port 29 which is connected through the hollow shaft 25 to the channel 21 and can be used for delivering fluids to the work site or for creating a negative pressure in the channel 21 to assist in drawing the obstruction material proximally. The flexible guidewire slidably passes through a close fitting hole formed at the proximal end of the rotary joint 28.

Figure 3 shows a first embodiment 111 of a flexible rotary catheter wherein the means for diametrical stabilization and for transmitting torque comprise an inner helix 61 wound in the direction of rotation (which means that moving along the coils of the inner helix in the direction of rotation illustrated by arrow 66 on Figure 3, while the helix is stationary, would cause advancing from the proximal end to the distal end). It can be visualized that when the inner helix is rotated in the direction of arrow 66, the proximal edge 61' of the ribbon which, due to the spacing between the coils contacts the obstructions material, will act on the material in the continuous passage as an inclined plane means and assist the obstruction material in moving proximally. Modifying the spacing or slightly bending the ribbon so as to increase its proximal edges protrusion into the continuous passage will increase the effectiveness of such inclined plane means. The winding of the inner helix would tend to diametrically expand when the motor 24 drives the flexible rotary catheter 111 in the direction of the arrow 66, however, a second outer helix 62 wound in the counter-rotation direction tends to contract and thereby restrain the expansion of the first helix 61 and assist it in transmitting torque.

It is desirable to minimize the catheters wall thickness to allow easy ingestion of cored obstruction material. The ribbon forming the outer helix is under longitudinal and radial tension whereas the ribbon forming the inner helix is under longitudinal and radial compression. As the catheter transmits torque the inner coil is subjected to bending and

buckling as well as compressive loads requiring the usage of a thicker ribbon for the inner coil than what is needed for the outer coil, this will optimize strength and flexibility while minimizing the wall thickness of the catheter.

A plastic wall 63 seals a channel 69 defined by the rotary catheter 111 so that negative pressure or fluid introduced at its proximal end would reach its distal end. Alternatively, a thin plastic layer can be inlaid between the helixes to minimize friction between them.

When the helixes are made of flat ribbon material as shown in Figure 3 they form a wall which does not seal fluids effectively but may be sufficient for the purposes of mechanically containing the cut obstruction particles without the plastic layer 63. Therefore, if fluid conveyance or suction through the flexible rotary catheter are not needed, the plastic wall 63 may be omitted to increase flexibility and decrease wall thickness of the flexible rotary catheter, and a thin slippery coating may be applied to the ribbons which are used to form the helixes, to minimize friction between the helixes and of the helixes with their surroundings.

A rotary coring means in the form of tubular blade 64 is made as an integral part of helixes 61 and 62, the last few coils of which are brazed together at their distal end and then sharpened.

Figure 6 shows a partially sectioned view of the second embodiment 113 of the flexible rotary catheter wherein the means for diametrically stabilizing and for transmitting torque comprise a helix 71 wound in the direction of rotation (such windings would tend to diametrically expand when the motor drives the flexible rotary catheter 113 in the direction of the arrow 77), and an external restraining member in the form of a wall 73 which restrains such expansion (the walls cross sectional marking is standard single line marking so as to not obscure a cord 76 which is integrated therein). The wall restraining action is reinforced by diametrical restraining means 76 in the form of cord made of, for example, nylon or aramid fibers which restrain the diametrical expansion of the helix 71 but have little effect on the walls ability to stretch along its longitudinal axis and therefore on its ability to bend as shown in Figures 1 and 2. The wall 73 defines a fluid worthy channel 79. A proximal edge 71' of the ribbon which, due to the spacing between the coils contacts the obstruction material, will act on the material in the continuous passage as an inclined plane means and assist the obstruction material in moving proximally. Modifying the spacing or slightly bending the ribbon so as to increase its proximal edges protrusion into the continuous passage will increase the effectiveness of such inclined plane means.

A rotary coring means in the form of a tubular blade 74 is made as an integral part of the helix 71, the last few coils of which are brazed together at their distal end and then sharpened, as shown in Figure 3.

The present invention provides the physician with a method to immediately and effectively intervene in what is often referred to as a "heart attack" which is commonly caused by an obstruction made of a soft fresh blood clot formed on an atherosclerotic plaque which has developed for several years. Currently, the presence of fresh blood clot, which has jelly like consistency, deters angioplasty since angioplasty may dislodge and release downstream some of the blood clots material causing additional arterial occlusions possibly at points which would be more difficult to treat or points where no alternate blood supply exists (at the point of the original obstruction, being an "old" obstruction, alternate blood supply may have developed). Currently, several pharmacologic treatments are being tested that dissolve the blood clot, after which angioplasty may be performed, however, because the present invention is effective in releasing and removing blood clots as well as atherosclerotic plaque it circumvents the delay and added risks that the pharmacologic treatment introduces, such as for example bleeding elsewhere.

The process for removing an obstruction made of a soft blood clot 15' formed on an atherosclerotic plaque from a blood vessel 12, comprises the following steps:

inserting into the blood vessel a flexible guidewire 17 and advancing it into the blood clot 15' which formed on the obstruction 15,

inserting into the blood vessel, over the flexible guidewire, the flexible rotary catheter 19 having a proximal end 13 and a distal end 14 with a rotary coring means affixed thereto,

advancing the distal end 14 to mechanically engage and unseat the blood clot 15' while applying suction to port 29 to such the blood clot 15' into the through hole 23, advancing the rotary coring means to rotatably engage and cut the atherosclerotic plaque of the obstruction 15, removing the system with the blood clot and the atherosclerotic plaque out of the blood vessel 12.

Claims

1. An atherectomy system (10) insertable into a human blood vessel (11) for coring and removing an obstruction therein, comprising:
   a flexible guidewire (17) insertable into said blood vessel (11);
   a flexible rotary catheter (19) having a continuous passage therethrough is rotatably disposed and slidable over said flexible guidewire

(17), said flexible rotary catheter having proximal and distal ends (13,14);
a rotary coring means (64) for cutting and ingesting obstruction material located at said distal end;
a coupling means (25) for rotating said flexible rotary catheter (19) around said flexible guidewire (17) located at said proximal end;
means for diametrically stabilizing and means (62) for transmitting torque in the form of closely spaced windings having distal and proximal edges (61'), said windings forming a skeleton of said flexible rotary catheter (19) and inclined plane means to assist in pulling the obstruction material into the catheter characterised in that the inclined plane means is provided by the proximal edges (61') of the closely spaced windings for contacting and assisting the obstruction material in moving proximally in the continuous passage.

2. An atherectomy system as claimed in claim 1, characterised in that the flexible rotary catheter is rotatably disposed in a sleeve.

3. An atherectomy system as claimed in any preceding claim characterised in that said flexible rotary catheter comprise a helix.

4. An atherectomy system as claimed in claim 3 characterised in that the helix is wound in the direction of rotation.

5. An atherectomy system as claimed in claim 4 characterised in that a diametrical restraining member restrains said helix.

6. An atherectomy system as claimed in claim 5 characterised in that said restraining member comprise an external helix wound in the counter rotation direction.

7. An atherectomy system as claimed in claim 5 or 6 characterised in that said restraining member comprise a plastic wall.

8. An atherectomy system as claimed in claim 7 characterised in that said wall contains diametrical restraining means.

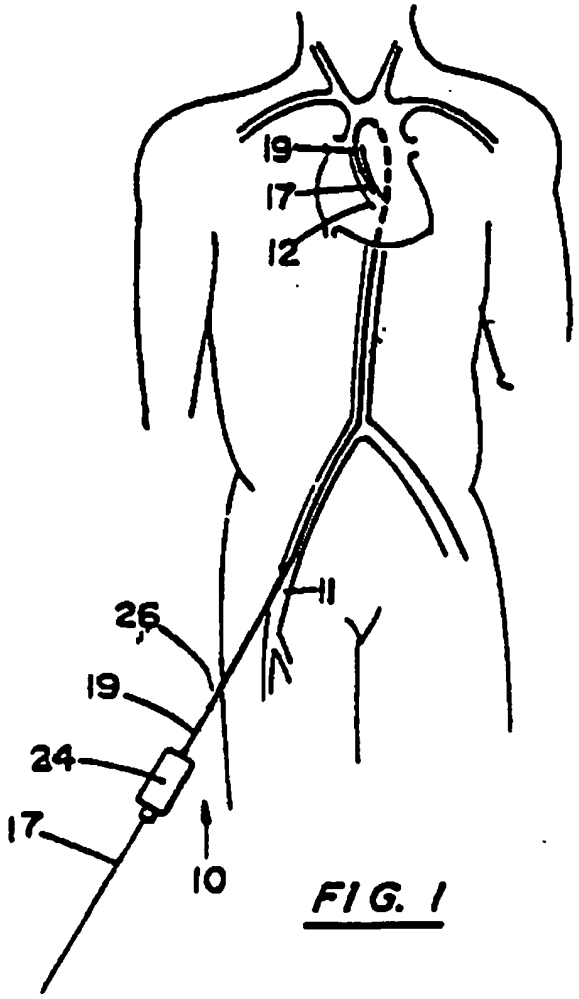

FIG. 1

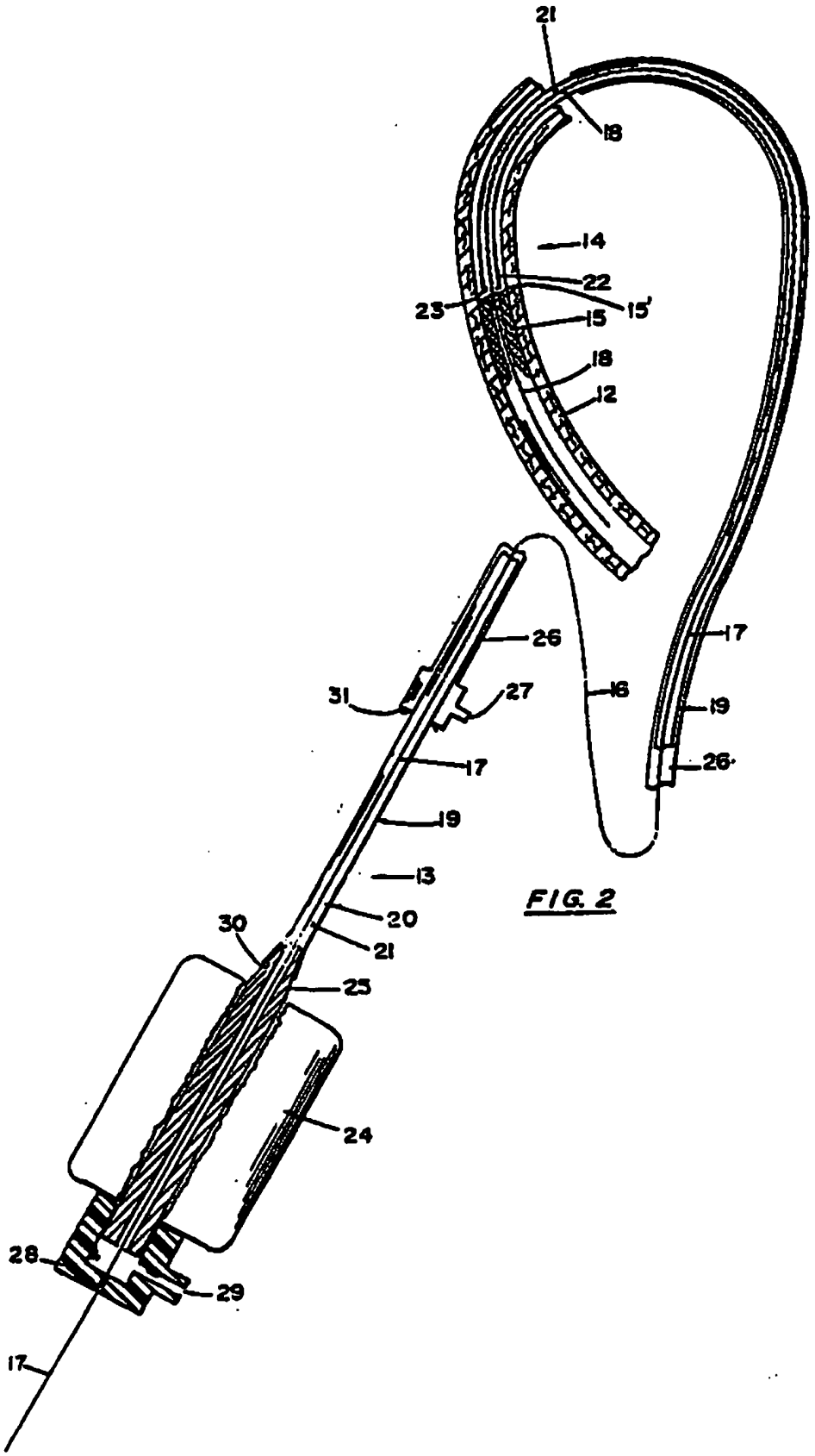
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FIG. 2

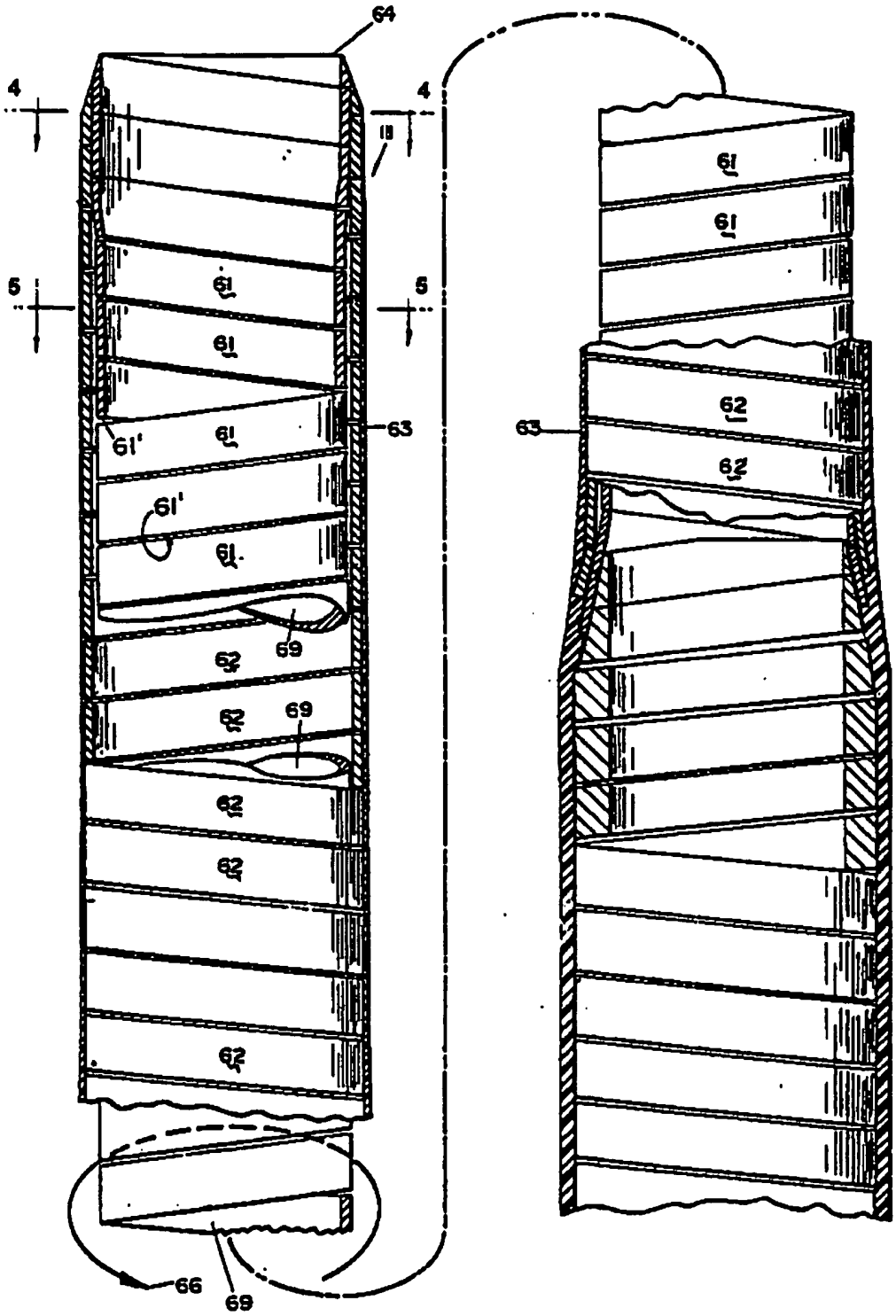

FIGURE 3

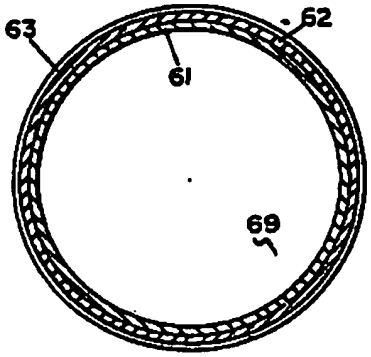

FIGURE 4

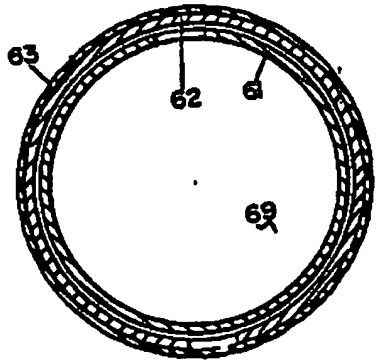

FIGURE 5

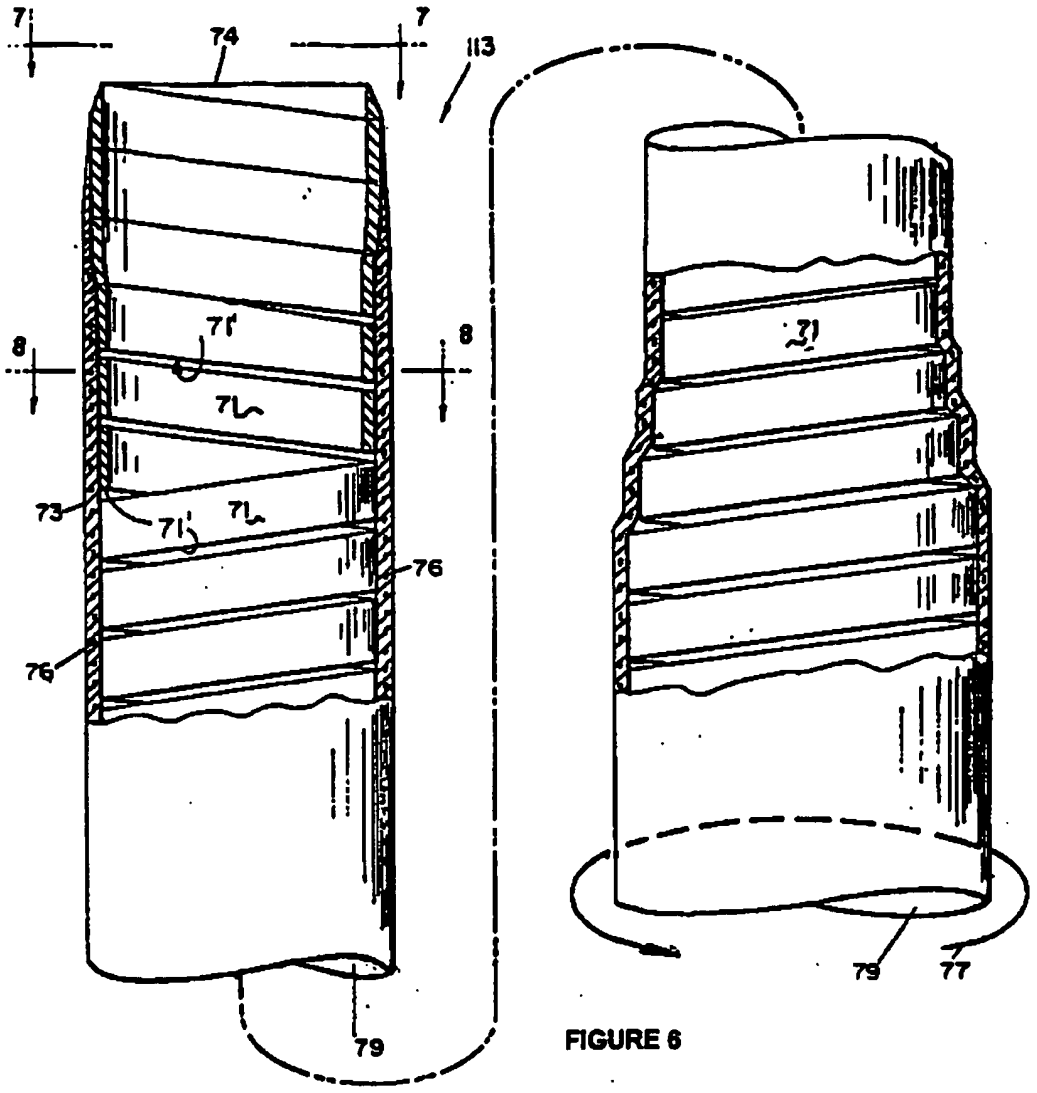

FIGURE 6

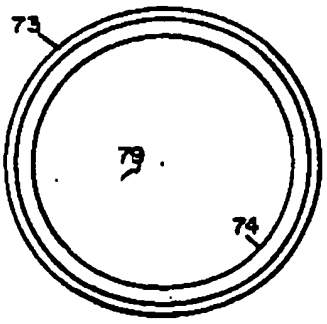

FIGURE 7

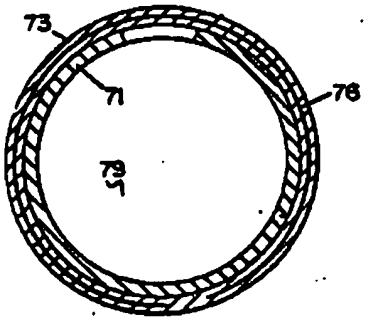

FIGURE 8